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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,752	09/18/2003	Tran Thong	117163-2	8009

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,752	THONG ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/05/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Preliminary Amendment, which was received by the Office on June 17, 2004. Claims 1-42 are pending.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/411,905, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, Claims 16-26 and 33-42 do not receive the benefit of the prior-filed application because there is not adequate support or enablement for "a means to determine a heart activity limit", "a heart activity limit-determining means which uses at least one of a plurality of heart activity parameters to determine the heart activity limit" or how the redetection threshold limit is "ignored when a fibrillation is determined after either a fibrillation or tachycardia treatment is started".

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on February 5, 2004 has been acknowledged and is being considered by the Examiner.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "means to determine a heart activity limit", "a heart activity limit-determining means which uses at least one of a plurality of heart activity parameters to determine the heart activity limit" and the method steps of how the redetection threshold limit is "ignored when a fibrillation is determined after either a fibrillation or tachycardia treatment is started" and method steps of tachycardia detection and treatment must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

5. The drawings are objected to because Figure 2 is inconsistent with Figure 1. Specifically, the Examiner suggests either modifying Figure 1 with a Prior Art label or changing Figure 1 to include an atrial electrode and defibrillation capabilities in the implantable medical device (currently pacemaker 15). Currently, the arrangement depicted in Figure 1 cannot carry out the arrangement of Figure 2 as stated by Applicant at page 4, paragraph 19 of the disclosure.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: step 1, step 2, step 3, step 4, step 5.

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because of the following informalities: there appears to be a grammatical error at page 1, paragraph 2, line 1 of the disclosure. The Examiner suggests changing "relates to an device" to "relates to a device". Appropriate correction is required.

9. The disclosure is objected to because of the following informalities: there appears to be typographical errors throughout page 5 of the disclosure. Specifically, in paragraphs 20-22, the Applicant makes reference to Figure 2, however it is clear from the disclosure that the reference should be to Figure 3 instead. Appropriate correction is required.

10. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: disclosure pertaining to "a means to determine a heart activity limit" and

"a heart activity limit-determining means which uses at least one of a plurality of heart activity parameters to determine the heart activity limit".

Claim Objections

11. Claim 1 is objected to because of the following informalities: there appears to be an inconsistency in the language of the claim. The Examiner suggests changing "a device for detecting the heart rhythm" at line three to "a heart rhythm detector for detecting the heart rhythm". The Examiner also suggests changing "the heart rhythm detecting device" in line 6 to "the heart rhythm detector". These changes are suggested to provide antecedent basis for the remainder of Claim 1 and for all depending claims where "the heart rhythm detector" is referred. Appropriate correction is required.

12. Claim 5 is objected to because of the following informalities: there is an inconsistency at the second line of the claim. At line 2, the Examiner suggests changing "comprises an electrode" to "comprises an atrial electrode" to provide antecedent basis for the "atrial electrode" mentioned in the fourth line of the claim. Appropriate correction is required.

13. Claims 11-15 are objected to because of the following informalities: there appears to be an inconsistency at the second and fourth lines of each claim. At line 2, the Examiner suggests changing "comprises an electrode" to "comprises a ventricular electrode" and at line 4, the Examiner suggests changing "connected to the atrial electrode" to "connected to the ventricular electrode" to provide consistency and antecedent basis in the claim. Appropriate correction is required.

14. Claims 16-22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel

the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, due to the Specification objections stated above and the 35 U.S.C. 112 rejections stated below, the Examiner is interpreting the claims to read "wherein the heart rhythm detector further comprises a means to determine the heart activity and detect whether the heart activity exceeds the fibrillation threshold limit or the redetection threshold limit" which is already presented in the limitations of Claim 1.

15. Claim 23 is objected to because of the following informalities: there appears to be a few grammatical and/or typographical errors in the claim. The Examiner suggests changing the second line of the claim to read "a heart activity limit-determining means that uses at least one of a plurality of heart activity parameters to determine the heart activity limit". Appropriate correction is required.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 16-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the specification does not describe a "means to determine a heart activity limit". The term "heart activity limit" is not a standard art-recognized term, and without further explanation, it is unclear exactly what is being determined. It is unclear, for example, if the term

"heart activity limit" applies to a threshold associated with heart rate (i.e. minimum or maximum beats per minute), a threshold associated with cardiac output (i.e. minimum or maximum volume of blood pumped by the ventricle per minute) or a threshold associated with the hearts electrical potential (i.e. a limit pertaining to a quantity associated with the amplitude of the QRS signal).

18. Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the specification does not describe a "heart activity limit-determining means that uses at least one of a plurality of heart activity parameters to determine a heart activity limit". As discussed above, the term "heart activity limit" is not a standard art-recognized term, and without further explanation, it is unclear exactly what parameters (i.e. measures of heart rate, cardiac output or electrical potential) are being used to determine such a "heart activity limit".

19. Claims 33-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the specification does not describe how the "redetection threshold limit is ignored when a fibrillation is determined after either a fibrillation or a tachycardia treatment is started". Currently, the limitations of Claims 33-34 contradict the limitations presented in Claims 1-2, 4, 27-28 and 31-32.

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16-22 recite the limitation "whether the heart activity exceeds" in the third line. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 1-22 and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Starkweather (U.S. 5,836,971). As to Claims 1 and 16, Starkweather discloses an implantable cardioverter/defibrillator/pacemaker (ICD), read as an arrangement 20 for treatment of rhythm disturbances, especially tachycardia and fibrillation of a heart 28 (see Starkweather Fig. 1, Abstract and column 1, lines 7-16 and 32-39) comprising a sense amplifier 42 coupled to a control/timing circuit 22, collectively read as a device for detecting the heart rhythm (i.e. the time that elapses between consecutive R-waves and/or P-waves) and determining when the lower limit of a fibrillation rate zone is exceeded, read as determining when a fibrillation threshold limit is exceeded, where the fibrillation threshold limit corresponds to a first predetermined heart rate value (see (Starkweather Fig. 3, column 7, lines 43-59, column 8, lines 22-42 and column 9, lines 3-44). The arrangement 20 of Starkweather further comprises a high voltage generator 26 and pulse generator 24, collectively read as a therapy delivery device, connected to the heart

rhythm detecting device (sense amplifier 42 and control/timing circuit 22) to begin to treat a fibrillation episode when the fibrillation threshold limit is exceeded (see Starkweather Fig. 1, column 7, lines 20-22, column 9, lines 55-67, column 10, lines 1-5, column 13, lines 64-67 and column 14, lines 1-4).

Starkweather further discloses that the fibrillation threshold limit is lowered, i.e. a rate zone below the current rate zone the heart rhythm has been classified into is "pulled up" into the current rate zone for redetection purposes to ensure that the patient will receive optimal therapy upon subsequent arrhythmia redetections, i.e. the therapy delivery device continues to treat the same fibrillation episode as long as the heart rhythm detecting device determines that the heart rate still exceeds the now "pulled up" lower limit of the fibrillation rate zone, read as a redetection threshold limit (see Starkweather column 9, lines 45-67, column 10, lines 1-23, column 11, lines 60-67 and column 14, lines 1-47). Starkweather expressly discloses this process for detection, treatment and redetection of a high rate ventricular tachycardia (VT) and generally discloses the process carried out by the arrangement 20 for detection, treatment and redetection of an arrhythmia in the other rate zones (i.e. low rate tachycardia or fibrillation) and by default, a fibrillation is detected when the detected heart rate exceeds a fibrillation threshold limit of approximately 240 bpm. After delivering of defibrillation shocks, the redetected heart rhythm is then compared to a redetection threshold limit of 200 bpm (the "pulled up" lower limit of the high rate VT rate zone into the current rate zone) and the therapy delivery device continues to treat the same fibrillation episode if the detected heart rhythm exceeds 200 bpm (i.e. the redetection threshold limit which is lower than the fibrillation threshold limit of 240 bpm and higher than a tachycardia threshold limit of approximately 150 bpm (see Starkweather Figs. 3

and 4A-4D, column 9, lines 45-67, column 10, lines 1-23, column 11, lines 60-67 and column 14, lines 1-47).

24. As to Claims 2 and 17, Starkweather discloses that the therapy deliver device delivers a series of electrical impulses to the heart 28 via electrodes 32, 38 and 40 (see Starkweather column 7, lines 20-32, column 9, lines 45-67, column 10, lines 1-23, column 11, lines 60-67 and column 14, lines 1-47).

25. As to Claims 3-4, Starkweather discloses that the heart rhythm detector (sense amplifier 42 and control/timing circuit 22) may detect an atrial fibrillation (see Starkweather column 6, lines 52-65, column 7, lines 43-59, column 8, lines 37-67 and column 9, lines 1-14) and that the therapy device may treat the atrial fibrillation (see Starkweather column 7, lines 1-19).

26. As to Claim 5, Starkweather discloses that the heart rhythm detector (sense amplifier 42 and control/timing circuit 22) may comprise an electrode 32 that may be situated in a region of an atrium of the heart 28 to detect the electrical activity thereof and that the therapy device including a pulse generator 24 and high voltage generator 26 may be connected to electrode 32 to deliver electrical pulses (an anti-tachycardia pacing regimen for example) to the atrium (see Starkweather column 7, lines 1-19).

27. As to Claims 6-10, Starkweather discloses that the heart rhythm detector (sense amplifier 42 and control/timing circuit 22) may detect a ventricular fibrillation that the therapy device may treat the ventricular fibrillation (see Starkweather column 6, lines 52-65, column 7, lines 43-59, column 8, lines 37-67 and column 9, lines 1-14).

28. As to Claims 11-15 and 18-22, Starkweather discloses that the heart rhythm detector (sense amplifier 42 and control/timing circuit 22) may comprise an electrode 32 that may be

situated in a region of a ventricle of the heart 28 to detect the electrical activity thereof and that the therapy device including a pulse generator 24 and high voltage generator 26 may be connected to electrodes 32, 38 and 40 to deliver anti-tachycardia pacing pulses/cardioversion/defibrillation therapy (see Starkweather column 7, lines 1-42).

29. As to Claims 27-30, Starkweather discloses that the heart rhythm detector (sense amplifier 42 and control/timing circuit 22) may determine when a tachycardia is occurring and the therapy device begins to treat the tachycardia when the tachycardia is detected, i.e. the detected heart rhythm is less than the lower limit for a high rate tachycardia but greater than the lower limit for a low rate tachycardia and pulse generator 24 emits an anti-tachycardia pacing regimen or the detected heart rhythm is less than the lower limit for fibrillation but greater than the lower limit for high rate tachycardia and the therapy delivery device delivers a first programmed shock for the VT high rate zone (see Starkweather Fig. 3 column 7, lines 20-32, column 9, lines 45-67, column 10, lines 1-23, column 11, lines 60-67 and column 14, lines 1-47).

30. As to Claims 31-32, Starkweather discloses that "pulling up" all lower rate zones into the corresponding rate zone permits the arrangement 20 to ensure that all subsequent arrhythmia redetection in a lower rate zone does not result in the delivery of a lower tier of therapy, e.g. a lower energy shock than the last tier of therapy delivered (see Starkweather column 13, lines 64-67 and column 14, lines 1-23). By default, the arrangement 20 of Starkweather is designed so that no tachycardia treatment (i.e. cardioversion shocks) is performed during a fibrillation treatment (i.e. high every defibrillation shocks).

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Duncan et al. (U.S. 5,882,352) (herein Duncan) discloses an anti-tachycardia stimulation device that adjusts rate zone thresholds based on the output of a physiological sensor.

Kroll (U.S. 6,445,949) teaches that the thresholds for rate zones may be changed (i.e. either increased or decreased) based on the success rate of the corresponding therapy delivered.

Pless et al. (U.S. 4,971,058) (herein Pless) discloses a cardiac therapy method with a duration timer which lowers post-therapy detection parameters so that if a high-rate tachycardia is detected, there will be continued treatment for the tachycardia notwithstanding the fact that it may revert to a lower rate tachycardia. In other words, the post-therapy detection parameters will detect what normally would have been a low rate tachycardia as if it were a high-rate tachycardia so that even if the arrhythmia slows to the range that would previously have been a low rate tachycardia, it is considered to be a high rate tachycardia episode. In this manner, taught by Pless, the therapies can be allowed to increase in effectiveness rather than going backwards in effectiveness.

Sun et al. (U.s. 6,230,055) (herein Sun) teaches adjustments of rate zones and the fibrillation detection zone boundary based upon the results of anti-tachycardia pacing in attempting to terminate arrhythmic episodes.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 04/13/06
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